

# EXHIBIT 100

# EXHIBIT 100

## Indianapolis, IN

Page 1

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

-----X

IN RE: PHARMACEUTICAL ) MDL No. 1456

INDUSTRY AVERAGE WHOLESALE ) Master File No.

PRICE LITIGATION ) 01-CV-12257-PBS

-----) Subcategory Case

THIS DOCUMENT RELATES TO: ) No. 06-11337

United States of America ex )

rel. Ven-A-Care of the ) Hon. Patti B. Saris

Florida Keys, Inc., et al. )

v. Dey, Inc., et al., Civil )

Action No. 05-11084-PBS, and) VIDEOTAPED DEPOSITION

United States of America ex ) OF THE INDIANA FAMILY

rel. Ven-A-Care of the ) AND SOCIAL SERVICES

Florida Keys, Inc., et al. ) ADMINISTRATION by

v. Boehringer Ingelheim ) CARL MARK

Corp., et al., Civil Action ) SHIRLEY, R.Ph.

No. 07-10248-PBS ) VOLUME I

-----X

DECEMBER 2, 2008

INDIANAPOLIS, INDIANA

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com

## Indianapolis, IN

Page 2	Page 4
<p>1 The videotaped deposition upon oral examination</p> <p>2 of CARL MARK SHIRLEY, R.Ph., a witness produced and</p> <p>3 sworn before me, Dana S. Miller, RPR, CRR, Notary</p> <p>4 Public in and for the County of Hendricks, State of</p> <p>5 Indiana, taken on behalf of the Defendants Dey and</p> <p>6 Defendant Abbott at the Hilton Indianapolis North</p> <p>7 Hotel, 8181 North Shadeland Avenue, Indianapolis,</p> <p>8 Indiana, on December 2, 2008, at 9:07 a.m.,</p> <p>9 pursuant to the Federal Rules of Civil Procedure.</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p>1 A P P E A R A N C E S (CONTINUED)</p> <p>2</p> <p>3 FOR THE DEFENDANTS, DEY:</p> <p>4</p> <p>5 KELLEY DRYE &amp; WARREN, LLP</p> <p>6 Douglas E. Julie, Esq.</p> <p>7 101 Park Avenue</p> <p>8 New York, NY 10178</p> <p>9</p> <p>10</p> <p>11 FOR THE DEFENDANT, ABBOTT LABORATORIES:</p> <p>12</p> <p>13 JONES DAY</p> <p>14 R. Christopher Cook, Esq.</p> <p>15 51 Louisiana Avenue, N.W.</p> <p>16 Washington, D.C. 20001-2113</p> <p>17</p> <p>18</p> <p>19</p> <p>20 ALSO PRESENT: James David - Videographer</p> <p>21</p> <p>22</p>
Page 3	Page 5
<p>1 A P P E A R A N C E S</p> <p>2</p> <p>3 FOR THE PLAINTIFF:</p> <p>4</p> <p>5 OFFICE OF INDIANA ATTORNEY GENERAL</p> <p>6 Gary Bippus, Esq.</p> <p>7 302 West Washington Street, Fifth Floor</p> <p>8 Indianapolis, IN 46204</p> <p>9</p> <p>10</p> <p>11 FAMILY AND SOCIAL SERVICE ADMINISTRATION</p> <p>12 Scott Linneweber, Esq.</p> <p>13 402 W. Washington Street, Room W451</p> <p>14 Indianapolis, IN 46204</p> <p>15</p> <p>16</p> <p>17 UNITED STATES ATTORNEY'S OFFICE</p> <p>18 SOUTHERN DISTRICT OF FLORIDA</p> <p>19 Ann M. St. Peter-Griffith, Esq.</p> <p>20 99 N.E. Fourth Street</p> <p>21 Miami, FL 33132</p> <p>22</p>	<p>1 I N D E X</p> <p>2</p> <p>3 WITNESS: CARL MARK SHIRLEY, R.Ph. PAGE</p> <p>4 EXAMINATION BY MR. DOUGLAS JULIE..... 009</p> <p>5</p> <p>6 E X H I B I T S</p> <p>7 NUMBER DESCRIPTION PAGE</p> <p>8 Exhibit Dey 501 - Subpoena..... 018</p> <p>9 Exhibit Dey 502 - Provider Agreement for</p> <p>10 Indiana Medicaid..... 117</p> <p>11 Exhibit Dey 503 - Drug Claim Form for</p> <p>12 Pharmacy..... 122</p> <p>13 Exhibit Dey 504 - Chapter 7 of Indiana Medicaid</p> <p>14 Provider Manual..... 146</p> <p>15 Exhibit Dey 505 - Government's Complaint..... 149</p> <p>16 Exhibit Dey 506 - State Plan Amendment,</p> <p>17 IN-00000045 - 0061..... 217</p> <p>18 Exhibit Dey 507 - State Plan Amendment,</p> <p>19 IN-00000082 - 0099..... 224</p> <p>20 Exhibit Dey 508 - Transmittal and Notice of</p> <p>21 Approval of State Plan</p> <p>22 Material, IN-00000016 - 0028. 229</p>

2 (Pages 2 to 5)

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com

## Indianapolis, IN

Page 6	Page 8
<p>1 EXHIBITS (CONTINUED)</p> <p>2 NUMBER DESCRIPTION PAGE</p> <p>3 Exhibit Dey 509 - State Plan Amendment,</p> <p>4 IN-00000100 - 0120..... 246</p> <p>5 Exhibit Dey 510 - Medicaid Pharmacy - Actual</p> <p>6 Acquisition Cost of Generic</p> <p>7 Prescription Drug Products,</p> <p>8 HHD022-0318 - 0333..... 302</p> <p>9 Exhibit Dey 511 - Excessive Medicare</p> <p>10 Reimbursement for Ipratropium</p> <p>11 Bromide Report..... 339</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p>1 defendants Dey, Inc., Dey L.P., Inc. and Dey,</p> <p>2 L.P.</p> <p>3 MR. BIPPUS: And -- go ahead.</p> <p>4 MR. COOK: I'm Christopher Cook from</p> <p>5 Jones Day representing Abbott.</p> <p>6 MR. BIPPUS: And Gary Bippus from the</p> <p>7 Office of the Indiana Attorney General.</p> <p>8 MR. LINNEWEBER: Scott Linneweber, L-I-</p> <p>9 N-N-E-W-E-B, as in boy, E-R, Family and Social</p> <p>10 Service Administration.</p> <p>11 MS. ST. PETER-GRIFFITH: Ann St. Peter-</p> <p>12 Griffith from the United States Attorney's</p> <p>13 Office, Southern District of Florida on behalf of</p> <p>14 the United States.</p> <p>15 VIDEOGRAPHER: Will our court reporter</p> <p>16 please swear or affirm the witness.</p> <p>17</p> <p>18 CARL MARK SHIRLEY, R.Ph.,</p> <p>19 having been first duly sworn to tell the truth,</p> <p>20 the whole truth, and nothing but the truth,</p> <p>21 relating to said matter, was examined and</p> <p>22 testified as follows:</p>
Page 7	Page 9
<p>1 PROCEEDINGS</p> <p>2</p> <p>3 VIDEOGRAPHER: On the record at 9:07</p> <p>4 a.m. on December 2nd, 2008. Here begins the</p> <p>5 videotaped deposition of Mark Shirley on behalf</p> <p>6 of the State of Indiana Family and Social</p> <p>7 Services Administration.</p> <p>8 This case regards the Pharmaceutical</p> <p>9 Industry Average Wholesale Price Litigation, MDL</p> <p>10 No. 1456, in the United States District Court,</p> <p>11 District of Massachusetts.</p> <p>12 This deposition is taking place at the</p> <p>13 Hilton Hotel, 8181 N. Shadeland Avenue,</p> <p>14 Indianapolis, Indiana.</p> <p>15 My name is James David, Certified Legal</p> <p>16 Video Specialist. And our court reporter is Dana</p> <p>17 Miller. We're both working with Henderson Legal</p> <p>18 Services.</p> <p>19 Will our counsel please state your</p> <p>20 appearance for the record.</p> <p>21 MR. JULIE: My name is Douglas Julie</p> <p>22 from Kelley, Drye &amp; Warren. And I'm counsel for</p>	<p>1 EXAMINATION</p> <p>2</p> <p>3 BY MR. DOUGLAS JULIE:</p> <p>4 Q. Good morning, Mr. Shirley. Thank you</p> <p>5 for making yourself available today. Can I ask</p> <p>6 you to please state and spell your name for the</p> <p>7 record.</p> <p>8 A. Yes. My name is Carl Mark Shirley,</p> <p>9 that's C-A-R-L M-A-R-K S-H-I-R-L-E-Y.</p> <p>10 Q. Thank you. And are you here today to -</p> <p>11 - are you here today on behalf of the Indiana</p> <p>12 Family and Social Services Administration?</p> <p>13 A. Yes.</p> <p>14 Q. You're their corporate designee?</p> <p>15 A. Yes.</p> <p>16 Q. Thank you. As I stated before, my name</p> <p>17 is Douglas Julie. I'm counsel for Dey, Inc.,</p> <p>18 Dey, L.P., Inc. and Dey, L.P. I'll refer to</p> <p>19 those three collectively today as Dey.</p> <p>20 Are you currently on any medications</p> <p>21 which might affect your memory?</p> <p>22 A. No.</p>

3 (Pages 6 to 9)

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com

## Indianapolis, IN

Page 142	Page 144
<p>1 reimbursement amounts into ingredient portion and</p> <p>2 a dispensing-fee portion?</p> <p>3 A. The reimbursement for pharmacy</p> <p>4 reimbursement is comprised of estimated</p> <p>5 acquisition cost plus dispensing fee, if</p> <p>6 applicable, MAC plus dispensing fee, if</p> <p>7 applicable, and usual and customary charge.</p> <p>8 So you had said aside from the state</p> <p>9 MAC -- or excuse me, the usual and customary</p> <p>10 piece, set that aside, then your two remaining</p> <p>11 possible pieces of the algorithm would be EAC and</p> <p>12 state MAC.</p> <p>13 Q. Okay. And on usual and customary-based</p> <p>14 reimbursement, there is no dispensing fee paid to</p> <p>15 providers?</p> <p>16 A. It's very important to understand that</p> <p>17 the providers submit a charge, which is his usual</p> <p>18 and customary charge, may or may not at that</p> <p>19 provider's discretion include a dispensing fee.</p> <p>20 That's totally up to the provider.</p> <p>21 Q. And if a provider submitted a claim</p> <p>22 that contains a usual and customary charge, that</p>	<p>1 submit. We do not tell them bill us only for</p> <p>2 some amount having to do with the drug and we,</p> <p>3 Medicaid, will put a dispensing fee on top of</p> <p>4 that. We never do that.</p> <p>5 Q. Okay. So -- all right, now I believe I</p> <p>6 understand. So you're saying that when a</p> <p>7 provider -- you know, I think you've said it.</p> <p>8 There's no reason to summarize.</p> <p>9 A. It's complicated.</p> <p>10 Q. You stated that one of the ways that</p> <p>11 Indiana reimburses for pharmaceuticals, Indiana</p> <p>12 Medicaid reimburses for pharmaceuticals, is that</p> <p>13 there is reimbursement for EAC --</p> <p>14 A. Yes.</p> <p>15 Q. -- and a dispensing fee. Is EAC</p> <p>16 estimated acquisition cost?</p> <p>17 A. That's correct.</p> <p>18 Q. When considering the adequacy of reim -</p> <p>19 - pardon me, strike that.</p> <p>20 When considering whether the state is</p> <p>21 providing adequate reimbursement for a covered</p> <p>22 product, does the state consider both the</p>
Page 143	Page 145
<p>1 -- I'm sorry. A provider can submit a claim that</p> <p>2 expresses its usual and customary charge in two</p> <p>3 parts, a part with a dispensing fee and another</p> <p>4 part?</p> <p>5 A. No, we do not allow for that. The only</p> <p>6 thing the program accepts and has instructed</p> <p>7 providers is to submit their usual and customary</p> <p>8 charge, which if the provider has a dispensing</p> <p>9 fee of their own, that is part of their usual and</p> <p>10 customary charge.</p> <p>11 Q. I'm not sure I understand what you mean</p> <p>12 by dispensing fee with respect to usual and</p> <p>13 customary charge.</p> <p>14 A. If a provider has a charge to you as a</p> <p>15 customer, they're going to typically make that</p> <p>16 charge up out of what they pay for the drug in</p> <p>17 some fashion somehow, and something that they use</p> <p>18 to cover their overhead and everything else</p> <p>19 associated with the running of the pharmacy.</p> <p>20 They blend that all together, and that becomes</p> <p>21 their usual and customary charge.</p> <p>22 That's what we have told them to</p>	<p>1 ingredient portion and the dispensing-fee portion</p> <p>2 as needing to be adequate?</p> <p>3 MS. ST. PETER-GRIFFITH: Object to the</p> <p>4 form.</p> <p>5 Q. Do you think of those issues together</p> <p>6 as providing that total reimbursement must be</p> <p>7 adequate, or does reimbursement for each</p> <p>8 individual component need to be adequate?</p> <p>9 MS. ST. PETER-GRIFFITH: Object to the</p> <p>10 form.</p> <p>11 A. Once again, my sense on this is that</p> <p>12 ultimately your reimbursement for the service</p> <p>13 must be adequate to ensure participation by</p> <p>14 providers. And my sense is that providers</p> <p>15 probably don't much care one way or the other</p> <p>16 which side of the equation is which, as long as</p> <p>17 what they get from Medicaid is sufficient for</p> <p>18 them to render service.</p> <p>19 So I think, you know, we act</p> <p>20 administratively in light of that. It makes</p> <p>21 sense to have a total reimbursement that is</p> <p>22 sufficient to maintain provider participation.</p>

37 (Pages 142 to 145)

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com

## Indianapolis, IN

Page 234	Page 236
<p>1 A. Yes.</p> <p>2 Q. Can you very briefly, because I may get</p> <p>3 to this later, can you tell me your understanding</p> <p>4 of the difference between brand and generic</p> <p>5 drugs?</p> <p>6 What was Indiana's understanding of the</p> <p>7 difference between brand drugs and generic drugs?</p> <p>8 A. Difficult to answer that question. The</p> <p>9 difference between brand and generic drugs,</p> <p>10 according to the FDA, is there is no difference.</p> <p>11 Generic drugs that are therapeutically</p> <p>12 substitutable for band-name drugs are the same.</p> <p>13 But if you're talking about reimbursement, that's</p> <p>14 a different issue. So I'm trying --</p> <p>15 Q. I am talking about reimbursement, sir.</p> <p>16 A. -- to find where you're going.</p> <p>17 Q. Thank you.</p> <p>18 A. So would you clarify the question.</p> <p>19 Q. Sure. This document, we've said,</p> <p>20 distinguishes between brand-name drugs and</p> <p>21 generic drugs for purposes of reimbursement;</p> <p>22 that's correct?</p>	<p>1 look at this, this and this equals generic, if</p> <p>2 you look at this, it's brand name.</p> <p>3 Q. Thank you. On this document it also</p> <p>4 appears that the state has instituted for the</p> <p>5 first time a state Maximum Allowable Cost</p> <p>6 program?</p> <p>7 A. Yes.</p> <p>8 Q. Is that -- is this your recollection as</p> <p>9 to chronologically the origin of the state MAC</p> <p>10 program?</p> <p>11 A. Yes.</p> <p>12 Q. And charges for federal upper limit and</p> <p>13 usual and customary-based reimbursement have been</p> <p>14 retained --</p> <p>15 A. Right.</p> <p>16 Q. -- in this plan?</p> <p>17 A. Yes.</p> <p>18 Q. Thank you. I'm going to ask you about</p> <p>19 the state MAC program a little later, but can I</p> <p>20 ask you now, why did Indiana switch from an AWP</p> <p>21 minus 10 EAC for all legend drugs to a bifurcated</p> <p>22 AWP minus 13 for brand-name drugs and AWP minus</p>
Page 235	Page 237
<p>1 A. Yes.</p> <p>2 Q. By generic drugs, does the plan mean to</p> <p>3 reimburse at a separate rate for innovator drugs</p> <p>4 and non-innovator drugs?</p> <p>5 A. In looking at this document, the only</p> <p>6 thing I can say is that there is clearly a</p> <p>7 difference in policy as to how the state is going</p> <p>8 to reimburse for brand-name drugs and for generic</p> <p>9 drugs.</p> <p>10 Q. Okay. If I was a provider or I worked</p> <p>11 for EDS and I wanted to know which drug fit the</p> <p>12 brand-name formula and which drug fit in for the</p> <p>13 generic formula, how would I go about determining</p> <p>14 that?</p> <p>15 A. I believe that would come from the</p> <p>16 First DataBank file that they use in claims</p> <p>17 processing.</p> <p>18 Q. So the distinction here is a</p> <p>19 distinction drawn on -- from First DataBank?</p> <p>20 A. First DataBank and if there is any</p> <p>21 algorithm that would be developed to pay elements</p> <p>22 from the First DataBank file that says if you</p>	<p>1 20 for generic drugs?</p> <p>2 A. I believe at the time the perception</p> <p>3 was that generic drugs, AWP information was not</p> <p>4 as accurate for generic drugs as it was for</p> <p>5 brand-name drugs, that is there was a greater</p> <p>6 spread on generic drugs.</p> <p>7 And if I also remember, it seems like</p> <p>8 there was some input from other states that using</p> <p>9 AWP's on generic drugs, you should have a higher</p> <p>10 percentage off of your AWP for your EAC.</p> <p>11 Q. When you say generic drug -- I'm sorry,</p> <p>12 strike that.</p> <p>13 You had stated that AWP information was</p> <p>14 not as accurate, though you didn't specify by</p> <p>15 what reference you were measuring its accuracy.</p> <p>16 Can you just tell me a little bit about what you</p> <p>17 were --</p> <p>18 A. I think there was a general perception</p> <p>19 that the AWP's for generic drugs were inflated.</p> <p>20 Seems like there was also some information from</p> <p>21 OIG or GAO or both or CMS or all three that</p> <p>22 questioned the use of AWP's on generics. And,</p>

60 (Pages 234 to 237)

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com



## Indianapolis, IN

Page 238	Page 240
<p>1 again, I'm going strictly by memory on this.</p> <p>2 It seems like that was part of the</p> <p>3 thrust behind the bifurcation of the</p> <p>4 reimbursement methodology for the two different</p> <p>5 types of legend drugs.</p> <p>6 Q. But you had specifically used the word</p> <p>7 that it was not as accurate. And it may very</p> <p>8 well be that you did not mean to use the word.</p> <p>9 But I'm just wondering whether when you said</p> <p>10 accurate, if you were considering whether AWP --</p> <p>11 when you think about AWP accuracy, with what are</p> <p>12 you referencing it as a guidepost? If something</p> <p>13 is inaccurate, it must be --</p> <p>14 A. I think it all has to do with this</p> <p>15 issue that people have called the spread, the</p> <p>16 relationship between the published AWP of a drug</p> <p>17 and an amount that a provider actually ends up</p> <p>18 paying for the drug.</p> <p>19 And it seemed like for generics, it was</p> <p>20 the case that there was this greater spread</p> <p>21 between the AWP and the actual acquisition cost.</p> <p>22 And I think that was probably what was behind the</p>	<p>1 which would have been 2002, and again I'm</p> <p>2 thinking of Myers &amp; Stauffer's role, they</p> <p>3 typically provided analytic support to the office</p> <p>4 on cost-containment initiatives. And this was</p> <p>5 probably driven partially at least by some type</p> <p>6 of cost-containment initiative. There may have</p> <p>7 been information provided by Myers &amp; Stauffer one</p> <p>8 way or the other about, you know, this is where</p> <p>9 the other states are on generics, and this is</p> <p>10 what the market looks like, and this is what this</p> <p>11 study shows. I don't know that for a fact one</p> <p>12 way or the other.</p> <p>13 It could be, possibly not, but that's</p> <p>14 one possible source of additional information,</p> <p>15 would have been input from Myers &amp; Stauffer.</p> <p>16 Q. Can you think of any other</p> <p>17 considerations that Indiana made at the time?</p> <p>18 A. Well, obviously, going through the</p> <p>19 rule- promulgation process, we would have</p> <p>20 considered all public comments.</p> <p>21 And not knowing right here what the</p> <p>22 public comments were that were made during the</p>
Page 239	Page 241
<p>1 taking generics to go to a minus 20 percent as</p> <p>2 opposed to say the minus 13 1/2.</p> <p>3 Q. Because Indiana wanted to get closer to</p> <p>4 -- get AWP-based reimbursement closer to the</p> <p>5 spread -- I'm sorry, strike that.</p> <p>6 Did you understand -- I'm sorry, did</p> <p>7 Indiana Medicaid understand at the time that it</p> <p>8 moved in 2002 from AWP to minus 10 to AWP minus</p> <p>9 20 for generics, did Indiana understand that it</p> <p>10 was not necessarily capturing all of the spread</p> <p>11 between average wholesale price and average</p> <p>12 acquisition costs in discounting average</p> <p>13 wholesale price?</p> <p>14 A. Repeat that question.</p> <p>15 Q. Did Indiana understand that when it</p> <p>16 moved in -- I'm sorry, strike that.</p> <p>17 Can you think of any other</p> <p>18 considerations that Indiana made other than</p> <p>19 information disclosed from CMS that caused it to</p> <p>20 make this switch to -- both to bifurcate brand</p> <p>21 and generic and to switch to generic minus 20?</p> <p>22 A. Looking at the time frame of this,</p>	<p>1 public hearing for the initiative, it's possible</p> <p>2 that there would have been other comments from</p> <p>3 the public. And the record of the public</p> <p>4 hearing, I'm sure, would show that.</p> <p>5 Q. What role did Indiana's understanding</p> <p>6 of the prices at which pharmacies could obtain</p> <p>7 pharmaceutical products play into the decision to</p> <p>8 reduce the reimbursement for generic drugs to</p> <p>9 minus 20 percent?</p> <p>10 A. State that again, please.</p> <p>11 MR. JULIE: Can you re-read that.</p> <p>12 (The requested material was read</p> <p>13 back by the reporter.)</p> <p>14 A. I quite sincerely do not understand the</p> <p>15 question.</p> <p>16 Q. Okay. Then I'll reask it a different</p> <p>17 way. When Indiana decided to reimburse for</p> <p>18 generic drugs at AWP minus 20 percent, did it</p> <p>19 consider in that decision-making process its</p> <p>20 knowledge of pharmaceutical prices available to</p> <p>21 provider pharmacies?</p> <p>22 A. I'm not certain of the analytic</p>

61 (Pages 238 to 241)

Henderson Legal Services, Inc.

202-220-4158

www.hendersonlegalservices.com